Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0233527	07/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Wvu Med Princeton Community Hospital Bluefield	500 Cherry St, Bluefield, WV	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A routine recertification survey was conducted at WVU Med Princeton Community Hospital Bluefield on July 7 & 8, 2026, by the West Virginia Office of Laboratory Services. The laboratory was surveyed under 42 CFR 493, Requirements for Laboratories and noncompliance was found. Specific deficiencies cited are explained below
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of 2024, 2025, and 2026 testing personnel (TP) competency assessment (CA) records, interview with the technical supervisor (TS1) and the laboratory director of operations, and exit interview with the laboratory administration team, the laboratory failed to assess the required initial training or competency for 2 of 12 testing personnel (TP) at the frequency established by the laboratory. Findings: 1. Review of laboratory policy "26.1110 D-GL Training and Competency Assessment" revealed prior to patient testing and reporting of patient results individuals "must have training and be evaluated for demonstration of the skills required for proper test performance" with this training documented on the "Induction Checklist". Section D.2 states the competency of employees should be assessed again approximately 6 months after patient testing begins. Section D.3 of the policy states established employees competency is assessed "at least annually". 2. Review of 2024, 2025, and 2026 TP competency assessment files revealed 2 of 12 TP lacked either a documented initial training checklist or CA at the frequency established by the laboratory in the 26.1110 D-GL policy as follows: TP8: annual CA signed 5/30/2024, TS1 could not locate

	documentation of another annual CA dated for 2025 TP10: began patient testing 3/30 /2026, TS1 could not locate the Induction Checklist initial training document 3. During an interview 7/7/26 at 11:00, the laboratory director of operations verified the lack of documented annual CA and initial hire training for the 2 TP. 4. An exit interview, 7/8/26 at 3:00 PM, with the laboratory administrative team confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) policy and procedure, 2026 College of American Pathologists (CAP) PT records, an interview with the laboratory operations manager, and an exit interview with the laboratory administration team, the laboratory failed to evaluate 3 of 3 unacceptable results in the C-A 2026 General Chemistry PT event. Findings: 1. Review of PT policy 26.1130 D-GL PT revealed "each unacceptable result or ungraded result must be evaluated and investigated in a timely manner to determine the impact on patient test results and correct problems identified." 2. Review of 2026 CAP PT records identified the following three unacceptable results with no documented evaluation in the C-A 2026 General Chemistry event: CHM-03 Calcium, serum reported result 12.10 acceptable range 8.72-10.73 CHM-02 Albumin reported result 5.6 acceptable range 4.5-5.4 CHM-02 Total protein reported result 10.0 acceptable range 8.2-9.7 3. Review of 2026 CAP PT records for event C-A 2026 General Chemistry revealed a tracking sheet for the event signed as reviewed by section supervisor (TS2) with no documented investigation of the three unacceptable results. 4. During an interview, 7/8/26 at 1:00 PM, the laboratory operations director could not locate a documented evaluation for the unacceptable results. 5. An exit interview with the laboratory administration team, 7/8 /26 at 3:00 PM, confirmed the findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observations of opened quality control (QC) material in the chemistry refrigerator during a tour of the laboratory, the manufacturer instructions for use (IFU) for QC materials, laboratory policies and procedures, interview with the technical supervisor (TS1), and exit interview with the laboratory administration, the laboratory failed to label two of two levels (3 and 1B) Cardiac Markers Plus Control LT QC material with the open date and correct expiration date. Findings: 1. During a tour of the laboratory, 7/7/26 at 4:00 PM, the state surveyor directly observed Cardiac Markers Plus Control LT (level 3 lot 1003143 and level 1B lot 1103145) QC material

	stored in the chemistry fridge at 2-8 degrees Celsius with no open date and a labeled expiration date of 7/20/26. During an interview, 7/7/26 at 4:05 PM, the TS1 stated the two bottles of QC material were currently in use for quality control on the Beckman Access II for Troponin I testing and on the Siemens Dimension analyzer for N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) testing and provided the state surveyor with two patient reports from 7/7/26 for Troponin I and NT-proBNP results using the opened QC: E3770441 and E3890384 2. Review of the Biorad IFU for Cardiac Markers Plus Control LT master lot 1003140 (level 3 1003143 and level 1B 1003145) revealed that once "thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius" the expiration of the QC material is 5 days for Troponin I and NT-proBNP analytes. 3. Review of the laboratory "Chemistry QC List" procedure revealed a chart stating each QC material used, the expiration of the material once opened, the analytes used for, and the storage conditions for the material. The procedure incorrectly states the expiration of Cardiac Markers Plus Control LT QC material as 20 days once opened and stored at 2-8 degrees Celsius for Troponin I and NT-proBNP testing. 4. An interview with TS1, 7/7/26 at 4:15 PM, verified the 2 bottles of Cardiac Markers Plus Control LT ((level 3 lot 1003143 and level 1B lot 1103145) QC material had no open date and the labeled expiration of 18 days from day observed (7/7/26, date of survey) did not follow the manufacturer IFU. 5. An exit interview with the laboratory administration team, 7/8/26 at 3:00 PM, confirmed the findings.